REMARKS/ARGUMENTS

Initially, the Applicants wish to thank the Examiner for her willingness to discuss this case in a telephonic interview of August 27, 2003 with the Applicants' attorney. During that interview, the Examiner's continued rejection under 35 U.S.C. § 112, first paragraph (written description) was discussed. Potential amendments to the claims were discussed. Such claim amendments were proposed to solely to expedite the prosecution of this application. The Examiner's Genbank references were also discussed, and the Examiner indicated that she would consider arguments regarding the relevancy of the references. The Examiner expressed a willingness to consider evidence of the ovarian cancer diagnostic properties of SEQ ID NOS: 199 and 214 as used in the presently claimed methods. Further the Examiner expressed a willingness to consider certain modifications to the claims and arguments regarding the written description rejection.

In the Office Action, the Examiner states that the probes of 10 bases are insufficient to be specific for the ovarian tumor gene described in SEQ ID NOS: 199 and 214. The applicant respectfully disagree with the Examiner's position that a probe of about 10 bases cannot be specific, however, to expedite the prosecution of this application, the Application have amended claim 22 to recite a probe selected from the group consisting of a) 20 to 363 contiguous nucleotides of SEQ ID NO 199, b) 20 to 1917 contiguous nucleotides of SEQ ID NO:214, and c) the complete complements of a) and b). The Applicants submit, that for the purposes of diagnosing ovarian cancer in a patient in need of such diagnosis, a probe having 25 continuous bases of SEQ ID 214 has been shown to be diagnostic. See declaration of Raymond L. Houghton, ¶ 4. Therefore, Applicants, submit that probes having about 20 contiguous nucleotides of SEQ ID NO:199, SEQ ID NO:214, and their complements are significantly specific to be used in the claimed methods of determining the presence of ovarian cancer in a patient.

The Examiner further alleges that the Applicants provide "no limits on the hybridization conditions, and no limits on the sequence identity required in order to be specific (for the claimed methods)." Office Action p. 2. The applicants respectfully traverse this

rejection. The claims recite that the probe hybridizes under moderately stringent conditions. Applicants provide written description of moderately stringent conditions beginning on page 27, line 13 of the specification. Moreover, the claims as presently constituted do not recite percent identity. Applicants, submit that the application does meet the written description requirement.

In additional support of her position that the Applicants have provided insufficient written description for the claimed invention, the Examiner states cites a number of Genbank submissions that have some number of contiguous bases in common with SEQ ID NOS 199 or 214. These submissions include Genbank BE385990, Genbank AI936926, Genbank AW149665, Genbank AW150789, and Genbank H06756. The examiner alleges that these because these sequences have some number of nucleotides in common with SEQ ID NOS: 199, 210, 211, and 214, the Applicants have not provided adequate written description of probes and primers used in the claimed methods of diagnosing ovarian cancer. The Applicants respectfully submit, that none of the cited sequences are diagnostic for any type of cancer or ailment. While these Expressed Sequence Tags were respectively isolated from melanotic melanoma, anaplastic oligodendroma, medulloblastoma, andenocarcinoma, and infant brain, none of the disclosures accompanying these sequences suggest that these sequences are over-expressed in the samples from which they were obtained or that they are otherwise diagnostic for any cancer or medical condition.

The Examiner further contends that the Applicants have not met the written description requirement set out in Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. Specifically, the examiner states, "the written description of genetic material 'requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed invention.'" Office Action at p. 4, citing Eli Lilly. Applicants note that Eli Lilly concerned claims directed to an organism containing human insulin cDNA. The Court found that the written description requirement was not met because the application did not disclose the sequence of the human insulin cDNA.

Unlike Lilly, the application in the present case provides the sequence the ovary specific gene O591S (SEQ ID NOS 199 and 214) that is shown to be over-expressed in ovarian cancer as compared to normal ovarian and other cancers. See Example 2. Moreover, the claims of the present application are not directed to a specific isolated polynucleotide or a cell

expressing a specific isolated cDNA, but rather to diagnostic methods using probes and primers to a sequence that Applicants have shown is over-expressed in Ovarian cancer. Given the high level of skill in the present art, one of ordinary skill in the art would be able design primers and probes for the using SEQ ID NOS 199 and 214. Therefore, Applicants description of the claimed methods is sufficient for the requirements of the second paragraph of Section 112.

The written description for such diagnostic methods is adequately provided in the specification as evidenced in the declaration of Raymond L. Houghton, Ph.D. a copy of which is submitted herewith. Dr. Houghton is familiar with the research that discovered the over expression of SEQ ID NOS 199 and 214 in ovarian cancer. Based upon the information provided in the specification of the present application, Dr. Houghton's team was able to design primers and probes that correctly detected ovarian cancer in multiple samples taken from patients. Importantly, these primers and probes did not detect ovarian cancer in samples obtained from healthy subjects and patients with a cancer other than ovarian cancer. See Declaration, ¶¶ 3, 4, & 6. Dr. Houghton's work shows that the present disclosure provides adequate written description for one of skill in the art to understand that Applicants' were in possession of the claimed invention at the time the application was filed.

The Commissioner is authorized to charge any fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 50-0597.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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EMB:kje

Application No. 09/970,966
Amendment Dated September 3, 2003
Reply to Final Office Action dated May 5, 2003
Enclosures:

Declaration of Raymond L. Houghton, Ph.D.
Form PTO/SB/17
Form PTO/SB/21
Form PTO/SB/22

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